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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,954	06/15/2001	Carla H. Kuhner	HER-0052	7577

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/881,954	KUHNER ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *22-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/20/01 & 6/3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-21 and 28-34 in the paper filed December 3, 2003 is acknowledged. The traversal is on the ground(s) that a search of the method of use claims (claims 22-27; "preventing, inhibiting, or terminating the growth of at least one microbe"; i.e. any microbe) would not constitute an undue burden on the examiner. At the outset it is noted that the last sentence of the distinctness paragraph (between Groups I and II) was in error, when it was stated that the "the method may be practiced by any of compounds 1-135 and a myriad of different biologically active agents". In actuality, the number of compounds was grossly underestimated by the examiner, and should have been at least 287,980 (based on 6 possible amino acids at positions 1 and 2, and at least 20 amino acids at positions 3 to 6 (=6 x 6 x 20 x 20 x 20 x 20); which does not contemplate uncommon amino acids, which the broadly claimed invention could also contemplate. Nevertheless, the same principle applies whether 135 compounds or 287,980 peptides are capable of use in the methods. Therefore, Applicants arguments are not found persuasive because, as described in the restriction, a myriad of different compounds could be used to treat a unlimited number of microbes. A search of each compounds for treating every potential microbe would be unduly burdensome on the examiner.

It is also noted that Applicant has still failed to elect a single compound, as required by the original restriction. Notwithstanding, and in order to move prosecution along, examination on the merits of Group I has been undertaken. Claims 1-21 and 28-34 are examined on the merits. Claims 22-27 (Group II) are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention is substantially drawn to "an antimicrobial composition comprising a plurality of hexapeptides"; namely at least 287,980 (based on 6 possible amino acids at positions 1 and 2, and at least 20 amino acids at positions 3 to 6 (=6 x 6 x 20 x 20 x 20 x 20); which does not contemplate uncommon amino acids, which the broadly claimed invention could also contemplate.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of ANY of the hexapeptides, because even though Figure 1 shows a 8 pages of proposed hexapeptides and B. cepacia growth, ONLY the 1st two amino acid residues is shown without the remaining 4 residues, thus the compounds could not be recreated as described (or searched for that matter). Additionally, Applicant has provided no compound list or sequence list been provided, which is essential in the case of peptides to allow a search of such peptides).

Thus, neither the claims nor the specification details the amino acid sequence of the compounds, in a form that can be recreated (or searched). With the substantial variability among the hexapeptides at residue positions 3 to 6, it is not clear whether any amino acid at any of the residues would allow such a hexapeptide beginning with the described 1st two residues, to work in the invention. One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the genus, namely all buffers and ranges.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112 1st Enablement

Claims 1-21 and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...".

> The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for any of the contemplated hexapeptides, for the following reasons:

The nature of the invention: The claimed invention is discussed above.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that, and as discussed in Applicant's specification, page 3, "U.S. Pat. No. 5,786,324 discloses peptides . . . [that] showed antimicrobial activity against Gram-negative bacteria including *Pseudomonas aeruginosa but were not active against* Burkholderia cepaica" (emphasis added).

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The specification does not teach what the specific hexapeptide structures are, either in the description or in Figure 1 or in the claims. It is unclear whether any amino acid residues at positions 3 to 6 would allow the hexapeptide to work as an antimicrobial against any microbe.

The breadth of the claims and the quantity of experimentation needed: Given the broad range of hexapeptides contemplated by the invention as capable of working generally as antimicrobials, and absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art; namely as to whether any hexapeptide can work as an antimicrobial (even with positions 1 and 2 defined), it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 and 28-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghten et al. (US 5,504,190).

Houghten et al. teach the use of hexapeptides with ARG-ARG at positions 1 and 2 [claimed options by Applicant], which may be in mixture, as antimicrobials (col. 43, lines 1-11 and col. 16, last ¶ to col. 17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun Chem. Corp (JP 53 028169) in view of Houghten et al. (US 5,504,190).

Sun Chem. Corp. teach a hexapeptide (TRY-HIS-TRY-LEU-GLU-LEU), with TRY and HIS at positions 1 and 2 respectively [claimed options by Applicant] with antimicrobial activity (abstract).

Houghten et al. is discussed above. Houghten et al. teach mixtures of hexapeptides as antimicrobials.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a plurality (i.e. mixture) of hexapeptides in the composition of Sun Chem. Corp., because Houghten et al. teach the advantageous use of mixtures of hexapeptides as antimicrobials.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
February 7, 2004

CHRISTOPHER R. TATE
PRIMARY EXAMINER